October 11, 2000

Prescription Drugs With Foreign Labels

Prepared for Rep. Henry A. Waxman

Minority Staff
Special Investigations Division
Committee on Government Reform
U.S. House of Representatives

The drug importation provisions in the Agriculture Appropriations bill contain several significant loopholes. One major loophole is created by the fact that foreign drug labels generally differ from the FDA-approved labels that must be used in the United States. In effect, the bill creates a labeling "Catch-22" for would-be U.S. importers.

As the bill is currently drafted, U.S. importers cannot import foreign drugs with labels that differ from the FDA-approved label. But U.S. importers cannot relabel the drugs with FDA-approved labels because doing so would violate the copyright and trademark protections held by the drug manufacturers. An amendment offered by Rep. Delauro to give U.S. importers the right to use the FDA-approved labels was voted down on a party line vote (9-6) during the conference.

The following discussion provides more information about this labeling "Catch 22," along with examples of foreign drugs with labels that differ from the FDA-approved labels.

Selling drugs without the FDA-approved label is misbranding. Prescription drug labels provide basic information on the drug, its formulation, the manufacturer and distributor, and how it is used. Every country has different labeling requirements. In the United States, when a company files an application for approval of a new drug, the company submits the label to FDA. Any deviation from the label submitted by the manufacturer without prior FDA approval constitutes misbranding of the drug. The penalties for misbranding under the Federal Food, Drug, and Cosmetic Act include fines and imprisonment.

Some drugs are sold under different names in the different countries. Prilosec, an ulcer medication made by Merck, was the number one selling drug in the United States in 1999. It is much more expensive in the United States ($120.45 for thirty 20 mg pills) than in Canada ($51.60) or Mexico ($34.50). However, in Canada and Mexico, the drug is sold under a different brand name: Losec. Because of this difference in names, the Canadian or Mexican labels are not the FDA-approved label. Bringing Prilosec into the United States with the Canadian or Mexican label is misbranding.

Attachment 1 displays the United States and Canadian labels for Prilosec/Losec.

Drug labels can be in different languages. In the United States, approved drug labels are in English (sometimes FDA also approves labels with some information in Spanish). In Mexico, labels are in Spanish; in Italy, labels are in Italian. Canadian drug labels are bilingual, in French

and English. Labels that are not in English, or that are bilingual English-French labels, differ from the FDA-approved label. Distributing drugs with these labels is misbranding.

Attachment 2 displays the United States and Canadian labels for Prozac, an antidepressant manufactured by Eli Lilly. The Canadian version of the label is a bilingual English-French label.

Drug labels can have different identification numbers. In the United States, all approved drugs receive an FDA identification number, known as a National Drug Code number. This number appears on virtually all U.S. labels. In Canada, however, approved drugs have a different number, a Drug Information Number (DIN). The DIN appears on all Canadian labels. Because the U.S. NDC code and the Canadian DIN are different, Canadian labels differ from the FDA-approved label, and selling a drug with a Canadian DIN in the United States constitutes misbranding.

Attachment 3 displays the United States and Canadian labels for Cipro, a popular antibiotic manufactured by Bayer. The different identification numbers are visible on the upper right corners of the labels.

Drugs are often distributed by different entities in different countries. When a manufacturer submits an application for approval of a new drug, the manufacturer must identify all the distributors of the drug. In many cases, the distributors of the drugs in the United States are different from the distributors in other countries. For example, the popular diabetes drug Glucophage is distributed in the United States by Bristol-Myers Squibb. However, when sold in Canada, the drug is distributed by Nordic Laboratories. If the Canadian distributor is not approved by FDA, drugs with labels listing this distributor differ from the FDA-approved label and cannot be sold in the United States.

Attachment 4 displays the United States and Canadian labels for Glucophage.

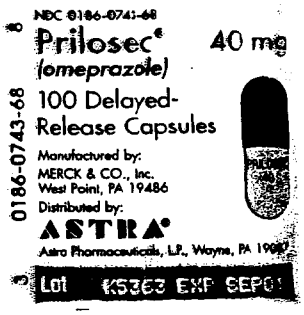
Drugs can have different indications. For some drugs, the indication information provided on labels from other countries is not the same as the U.S. information. For example, Dilantin, an anticonvulsant manufactured by Parke-Davis, contains the following information on the Canadian label:

> Adults, initially 1 capsule 3 times daily with subsequent doses individualized to a maximum of six doses daily. Usual maintenance dose is 3 to 4 capsules daily. Children over 6 years of age, 1 capsule three times daily or as directed by physician.

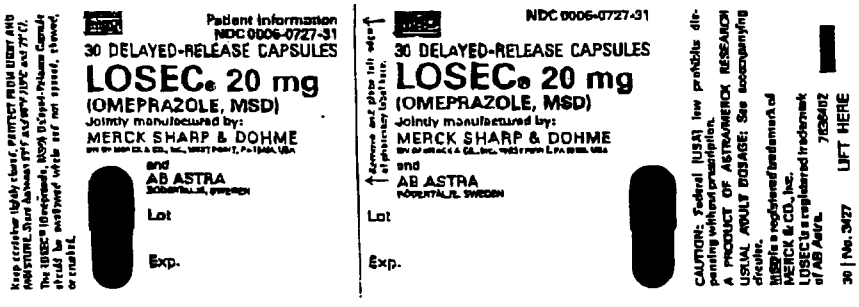
The U.S. label contains slightly different information for adults and no dosage information for children. The U.S. label states: “Adults, 1 capsule three or four times daily or as directed.” Because the United States and Canadian versions of the drug label contain different dosage information, the drug cannot be sold in the United States with the Canadian label.

Attachment 5 displays the United States and Canadian labels for Dilantin.

United States Label

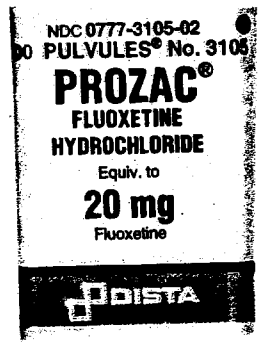


Canadian Label

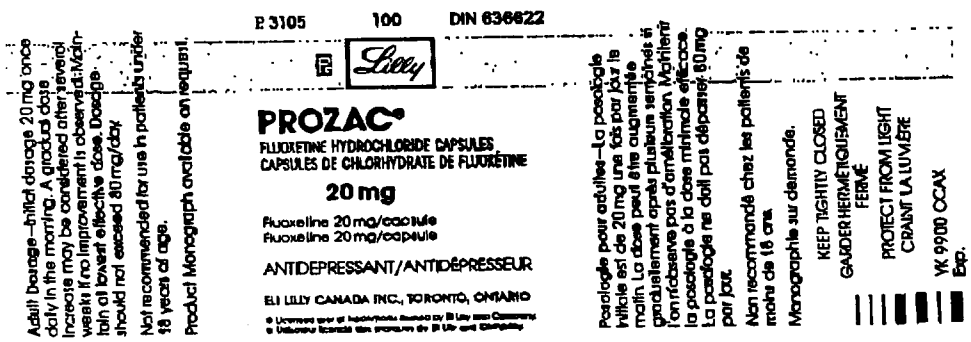


Attachment 1

United States Label

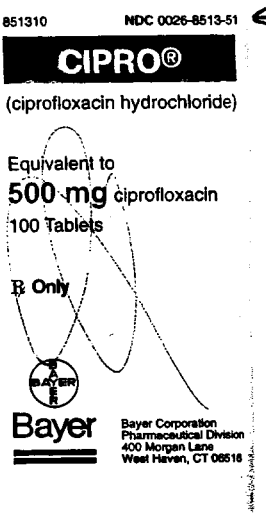


Canadian Label

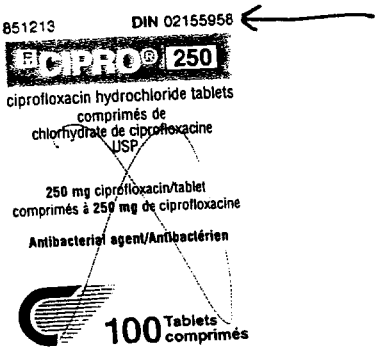


Attachment 2

United States Label

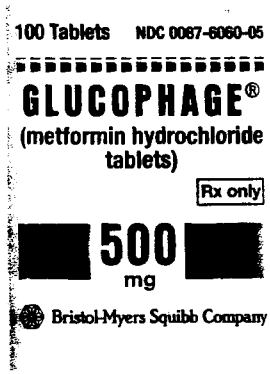


Canadian Label



Attachment 3

United States Label



Canadian Label

No. 2509 500 comprimés tablets

Chaque comprimé contient:
Chlorhydrate de Metformine .....500 mg

POSOLOGIE

ADULTES: 1 comprimé (0.5 g) 3 à 4 fois par jour durant les repas. La dose maximale quotidienne de 2.5 g ne devrait pas être dépassée. L'augmentation de la dose doit être graduelle afin de minimiser les troubles gastro-intestinaux.

Monographie disponible sur demande.

Lipha

FABRIQUÉ SOUS LICENCE DE LIPHA SA, LYON, FRANCE

7 70258 25094 5

Pr **GLUCOPHAGE®**

Comprimés de
CHLORHYDRATE DE METFORMINE / METFORMIN HYDROCHLORIDE
Tablets
Norme Nordic Standard
500 mg
Antihyperglycémiant
Antihyperglycemic
DIN 00314552

NORDIC
LABORATOIRES NORDIC INC
NORDIC LABORATORIES INC
Laval, QC, Canada H7L 3M7

Each tablet contains:
Metformin Hydrochloride .....500 mg

DOSAGE

ADULTS: 1 tablet (0.5 g), 3 to 4 times daily during meals. A maximum daily dose of 2.5 g should not be exceeded. Dosage should be increased gradually to minimize gastrointestinal disorders.

Product monograph available upon request.

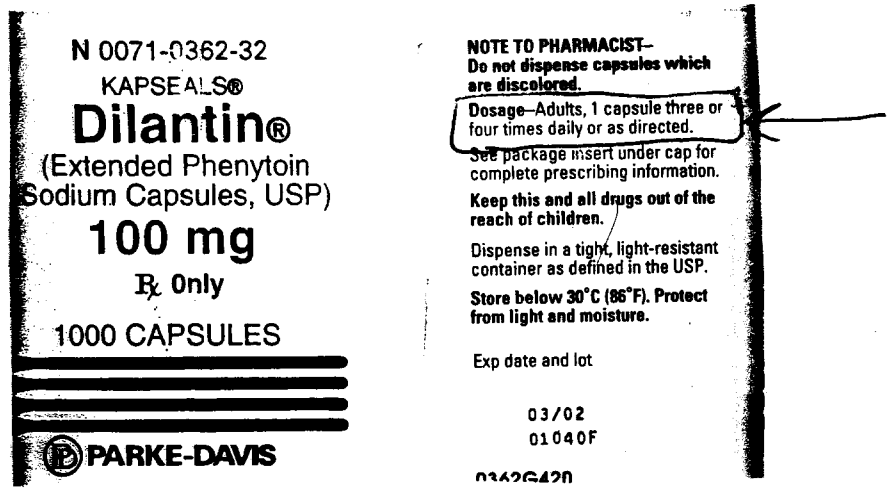
Lipha

MADE UNDER LICENCE FROM LIPHA SA, LYON, FRANCE

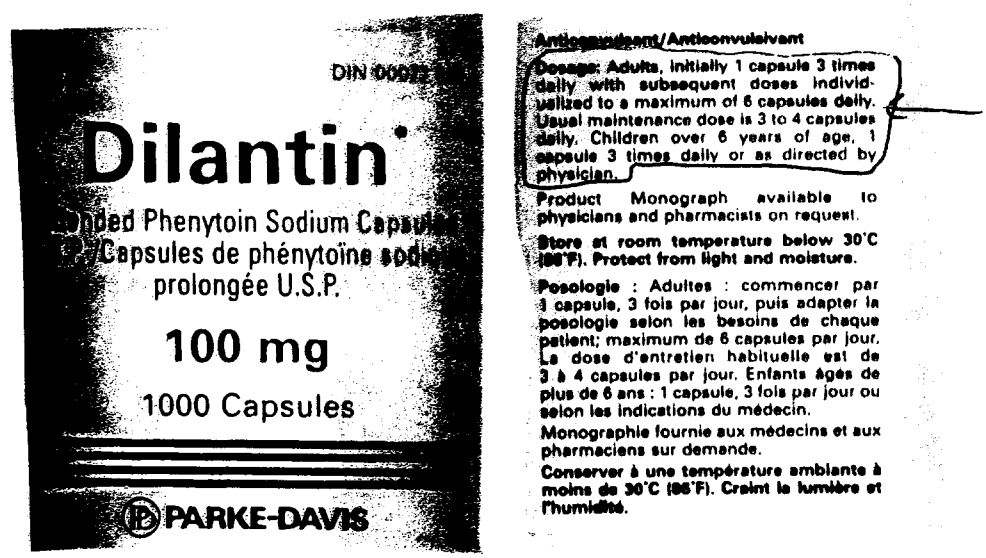
E-8208-900-0

Attachment 4

United States Label



Canadian Label



Attachment 5